K072378
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510(k) Summary

NOV 0 9 2007

510(k) Number: K072378
Date: 8/21/2007
Company: Arthrex, Inc.
Address: 1370 Creekside Blvd., Naples, FL 34108-1945
Telephone: (239) 643-5553
Facsimile: (239) 598-5508
Contact: Ann Waterhouse

Trade Name: Arthrex ProWick™
Common Name: Wound dressing
Classification: wound dressing
Product Code: FRO
Predicate Devices: K033900, K050726, K062559, and K062212

Description:
The Arthrex ProWick™ device is a post-surgical antimicrobial wound dressing containing a variety of elements such as elastic straps, waterproof bandages, dressing, foam islands infused with a silver based antimicrobial agent, and a reusable cold pack, sold sterile.

Indications for Use:
The Arthrex ProWick™ Postoperative Wound Dressing is indicated for the management of post-surgical wounds and the silver component present in the dressing may act as a barrier to colonization of *E coli, S aureus, A. niger, C. albicans,* and *P. aeruginosa* within the dressing.

By definition, substantial equivalence means that a device has the same intended use and technical characteristics as the predicate device, or has the same intended use and different technological characteristics, but can be demonstrated to be as safe and effective as the predicate device. The difference between the Arthrex ProWick™ and the predicate devices with similar indications and technological characteristics do not raise any questions regarding the safety and effectiveness of the implant. Furthermore, the materials are well characterized and have been used in predicate devices with similar indications. The devices, as designed, are as safe and effective as predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 9 2007

Arthrex, Inc.
% Ms. Ann Waterhouse, RAC
Regulatory Affairs Project
Manager
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K072378
Trade/Device Name: Arthrex ProWick™
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 3, 2007
Received: October 22, 2007

Dear Ms. Waterhouse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

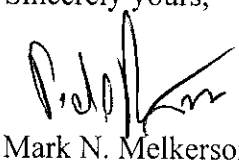
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Indication for Use Form

510(k) Number: K072378

Device Name: Arthrex ProWick™

Indications for Use:

The Arthrex ProWick™ Postoperative Wound Dressing is indicated for the management of post-surgical wounds and the silver component present in the dressing may act as a barrier to colonization of *E coli, S aureus, A. niger, C. albicans,* and *P. aeruginosa* within the dressing.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restora
and Neurological Devices

510(k) Number K072378